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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,694	05/22/2000	Anne Sorensen	Novo-029	3706

7590

12/15/2003

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EXAMINER

HON, SOW FUN

ART UNIT PAPER NUMBER

1772

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/577,694

Applicant(s)

SORENSEN ET AL.

Examiner

Sow-Fun Hon

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 43-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/06/03 has been entered.

#### ***Response to Amendment***

##### ***Withdrawn Rejections***

2. Claims 1-42 is cancelled in Paper # 12 (filed 10/06/03) thus rendering moot the corresponding rejections in Paper # 9 (mailed 04/08/03).

##### ***New Rejections***

##### ***Claim Rejections - 35 USC § 112***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 59-60 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step in the process of claim 59 is “-mixing the butyl based rubber and thermoplastic polymer together to form the stopper material”.

***Claim Rejections - 35 USC § 102***

5. Claims 43-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasai et al.

Kasai et al. teaches a stopper *comprising* an injection-mouldable blend of 30 to 90 weight % partially crosslinked butyl based rubber and up to 30 weight % thermoplastic polymer (polyolefin) (column 1, lines 45-55) which overlaps the combination of the claimed range of 70-90 % by weight of butyl rubber and 30-10 % by weight of thermoplastic polymer. The polymer (polyolefin) is polypropylene or polyethylene (column 1, lines 60-65). The butyl based rubber is a halogenated one (column 1, lines 50-55) such as a bromobutyl rubber (column 2, line 65).

Kasai et al. teaches that the butyl rubber alone is subject to permanent set and cannot provide a stopper for hermetically sealing a medical container (column 2, lines 30-40) thus teaching that a stopper made from a combination of the butyl rubber and another component provides for a hermetically sealed container resulting in a reduced leakage of substances compared to a stopper made from butyl rubber alone.

Kasai et al. teaches that the butyl based rubber is at least partially crosslinked (column 1, lines 50-55), is blended with up to 30 % polypropylene or polyethylene (column 1, lines 45-55), and that the stopper is injection moulded (column 3, lines 55-65), all of which read on the composition and process of stopper manufacture as presently claimed by Applicant. Thus it appears that the stopper of Kasai et al. has a hardness of 40-80 Shore A in conformance with ASTM D2240, 5 sec., 1991 in the absence of factual data.

Kasai et al. teaches a medical container with non-flexible (hard) walls (column 1, lines 10-15). The figures show that the stopper has a circular cross-section, and that the container

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comprises a distal and a proximal end, and at least one wall defining an interior space for storing liquid medicament (figures and column 5, lines 40-50).

Kasai et al. provides an example of the process whereby the butyl rubber and the thermoplastic polymer are mixed (kneaded with a mixer) at 150 to 250 °C to pelletize them and then injection moulded at preferably 200 to 220 °C to form the stopper (column 3, lines 55-60). Since injection moulding is normally done at temperatures above melting point of the material that is being injection moulded, the pelletizing step above conducts all three steps of heating the butyl based rubber; melting the thermoplastic polymer and homogenizing the material.

Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (*Fed. Cir.* 1985). In the instant case, Fig. 5 of Kasai et al. shows that stopper 21 is in container body 22, and any way of pushing the stopper in, whether the applied force to the stopper is through a rod or palm of a hand results in a stoppered container. It can also be seen that the stopper can only glide longitudinally into the container body.

### ***Claim Rejections - 35 USC § 103***

6. Claims 57, 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. in view of Rheude (US 2,507,680).

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Kasai et al. has been discussed above and teaches the stopper comprising the injection-mouldable material made of a combination of 70-90 % by weight of butyl based rubber and 30-10 % by weight of thermoplastic polyethylene wherein the combination of the butyl based rubber and the thermoplastic polymer results in a reduced leakage of substances compared to the leakage of substances from a stopper made from butyl based rubber alone. Kasai et al. also teaches the process comprising injection moulding by which the stopper is made, but fails to teach that the stopper is moulded onto a rod by means of two-component injection moulding.

Rheude teaches a stopper for a container (bottle) which has a pusher rod 6 (column 2, lines 1-5). It can be seen in Fig 3 that the pusher rod results in the stopper being completely inserted into the neck of the container.

Anyone who has tried to shove a rubber stopper into a bottle neck knows how difficult it is to push it in completely. Rheude has shown that it would have been obvious to one of ordinary skill in the art to have attached a pusher rod to the stopper of Kasai et al. in order to facilitate insertion of the stopper into the neck of the container.

It would then have been obvious to one of ordinary skill in the art to have moulded the stopper onto a rod during the injection moulding step in the process of Rheude, which step would then have been termed two component injection moulding.

### ***Response to Arguments***

7. Applicant's arguments with respect to the cancelled claims have been considered but are moot in view of the new ground(s) of rejection.

8. However, in order to advance prosecution, Applicant's arguments with respect to Kasai et al. are addressed below.

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9. Applicant argues that the present invention relates to a stopper material of two components, wherein a balance of the two above-mentioned characteristics has been provided.

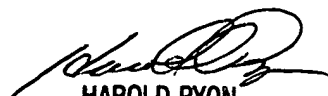
Applicant is respectfully reminded that the term "comprising" in claim 43, 54, 59 encompasses the two components, namely the butyl based rubber and the thermoplastic polymer, along with other components. Thus Kasai et al. continues to be valid prior art. The limitation of "A stopper consisting essentially of" is more appropriate in limiting the claims.

10. Applicant argues that the thermoplastic elastomer does not comprise a polyethylene or a polypropylene such as the thermoplastic polyolefin of the present invention. Applicant is respectfully apprised that the term "polyethylene" is broadly interpreted to include olefin copolymers of ethylene with a major component of ethylene monomer units. However, it appears that Applicant may be further clarifying that the terms "polyethylene" and "polypropylene" apply only to the respective homopolymers. Confirmation is requested.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

  
Sow-Fun Hon  
12/5/03

  
HAROLD PYON  
SUPERVISORY PATENT EXAMINER  
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